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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/056,623 | 01/28/2002 | Gary E. Rehm | MSE #2620 | 9413 |

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| EXAMINER | |
|---|---|
| RAMILLANO, LORE JANET | |
| **ART UNIT** | **PAPER NUMBER** |
| 1743 | |

| MAIL DATE | DELIVERY MODE |
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| 05/16/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/056,623 | REHM, GARY E. | |
| | Examiner | Art Unit | |
| | Lore Ramillano | 1743 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *30 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) *29-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/27/03,6/5/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of claims 1-28 (Group I) in the reply filed on 10/30/06 is acknowledged. However, because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 29-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Although applicant elected the above claims with traverse, the election was made **without** traverse for the reason stated above.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 200

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The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. **Claims 1, 3, 8, 10, 15-17, 23-25, and 28** are rejected under 35 U.S.C. 102(b) as being anticipated by Howard et al. ("Howard," US 5654803).

As to claims 1 and 3, Howard teaches a method of using an infrared reading comprising the step of: determining if the infrared reflectance of one or more reagents are within an acceptable predetermined range; and wherein the reagents are leukocyte, glucose and albumin (i.e. column 3, lines 41-54; column 7, line 9 to column 8, line 62).

As to claims 8 and 10, Howard teaches an automated method of using an infrared reading comprising the step of: determining if the test strip possess specified reagents, locating the position of the reagents on the strip; reading the infrared reflectances from the reagent positions; and determining if the infrared reflectances are within an acceptable predetermined range; and wherein the reagents are leukocyte, glucose and albumin (i.e. column 3, lines 41-54;column 3, line 63 to column 4, line 7).

As to claims 15-17, 23-25, and 28, Howard teaches an automated method of reading a test strip comprising: (a) providing a test strip (fig. 2) having at least one test field on its surface that reflects light at a specific range of wavelengths and at least two distinct marker fields on the same surface of the test strip as the test field, the marker fields reflecting light at different ranges of wavelengths from each other and from the test field in a coded sequence of ranges of wavelengths (i.e. fig. 5, column 4, line 55 to column 5, line 47); (b) introducing the test strip into a strip reading device (fig. 1) equipped with a reading means for both the test field and the marker fields, the reading

means comprises a light source (46, fig. 3) as a transmitter and a light sensitive element as receiver (fig. 4), the receiver being capable of differentiating between the ranges of wavelengths at which the test field and the marker fields reflect, the strip reading device also being equipped with means for correlating the coded range of infrared wavelength sequence of reflected light with preprogrammed information concerning the test strip, the correlating means being in operative communication with a receiving means (figs. 6-7, i.e. column 6, line 36 to column 7, line 62), the reading device having means for moving the test strip and the receiving means relative to one another so that the reflectance of the test field and the marker fields can be individually read by the reading means (means for moving, i.e. column 6, lines 49-54); (c) allowing the ranges of wavelengths values reflected by the test field and the marker fields to be individually read by the reading means; (d) allowing the reading means to communicate the coded infrared sequence of spectral reflectance values reflected from the marker fields to the correlating means and allowing the correlating means to correlate the infrared sequence of reflected range of wavelength values with the preprogrammed information concerning the test strip; and (e) allowing the reading means to communicate the reflected range of infrared wavelength values to the correlating means and allowing the correlating means to determine for one or more of the reagents disposed on the test strip (figs. 6-7, i.e. column 6, line 36 to column 7, line 62).

Howard further teaches the following: the test strip is placed on a feed table (20, fig. 2); the reagents comprise leukocyte, glucose and albumin (i.e. column 3, lines 41-54); the range of wavelength value reflected from the test field and the marker fields are

read by moving the test strip and the reading means relative to each other (i.e. column 4, lines 1-8); the feed table is movable in relation to the reading means (i.e. column 4, lines 1-8); the reading means is capable of acquiring spatial and spectral reflectances across the length of the test strip (i.e. fig. 3); and the marker fields comprise bars that are substantially parallel to each other and are substantially perpendicular to the longitudinal axis of the test strip (i.e. fig. 5).

5. **Claims 1-3, 5, 7-10, 12, and 14** are rejected under 35 U.S.C. 102(e) as being anticipated by Corey et al. ("Corey," US 6316264).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

As to claims 1-3, 5 and 7, Corey teaches a method of using an infrared reading comprising the step of: determining if the infrared reflectance of one or more reagents are within an acceptable predetermined range; the step of aborting the test if the infrared reflectances are not within the range; the reagents are leukocyte, glucose and albumin; the predetermined infrared reflectance range of glucose reagent is from 75 to about 95 percent infrared reflectance; and the test will be aborted if the test strip is more than about 0.02 inches from a central location on a feed table or if the test strip is incompletely inserted by more than about 0.05 inches (i.e. column 3, lines 41-54;

column 7, line 9 to column 8, line 62; column 13, lines 19-27; column 16, lines 13-23; column 18, lines 60-63).

As to claims 8-10, 12, and 14, Corey teaches an automated method of using an infrared reading comprising the step of: determining if the test strip possess specified reagents, locating the position of the reagents on the strip; reading the infrared reflectances from the reagent positions; and determining if the infrared reflectances are within an acceptable predetermined range; the step of aborting the test if the infrared reflectances are not within the range; the reagents are leukocyte, glucose and albumin; the predetermined infrared reflectance range of glucose reagent is from 75 to about 95 percent infrared reflectance; and the test will be aborted if the test strip is more than about 0.02 inches from a central location on a feed table or if the test strip is incompletely inserted by more than about 0.05 inches (i.e. column 3, lines 41-54; column 7, line 9 to column 8, line 62; column 13, lines 19-27; column 16, lines 13-23; column 18, lines 60-63).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. **Claims 4, 6, 11, 13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Corey.

While Corey teaches a method comprising the predetermined infrared reflectance range of glucose reagent is from 75 to about 95 percent infrared reflectance, Corey does not specifically teach a method comprising having predetermined infrared reflectance ranges for leukocyte and albumin. It would have been obvious to a person of ordinary skill in the art to incorporate predetermined infrared reflectance ranges for leukocyte and albumin into Corey's automated method because having predetermined values of the analyte being tested for, such as leukocyte and albumin, in Corey's detection apparatus would allow a user to quickly determine the results of each sample

since the information pertaining to the predetermined values are stored in the detection apparatus.

10. **Claims 18-22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Howard in view Corey.

The teachings of Howard are stated above in paragraph 6. Howard does not specifically teach aborting the method if the infrared reflectances for one or more reagents are not within the predetermined range; aborting the test if the test strip is more than about 0.2 inches from a central location; and having predetermined infrared reflectance ranges.

Corey teaches an automated method of using an infrared reading comprising the step of: determining if the test strip possess specified reagents, locating the position of the reagents on the strip; reading the infrared reflectances from the reagent positions; and determining if the infrared reflectances are within an acceptable predetermined range; the step of aborting the test if the infrared reflectances are not within the range; the reagents are leukocyte, glucose and albumin; the predetermined infrared reflectance range of glucose reagent is from 75 to about 95 percent infrared reflectance; and the test will be aborted if the test strip is more than about 0.02 inches from a central location on a feed table or if the test strip is incompletely inserted by more than about 0.05 inches (i.e. column 3, lines 41-54; column 7, line 9 to column 8, line 62; column 13, lines 19-27; column 16, lines 13-23; column 18, lines 60-63).

It would have been obvious to a person of ordinary skill in the art to modify Howard by incorporating the step of aborting the method if the infrared reflectances for

one or more reagents are not within the predetermined range, aborting the test if the test strip is more than about 0.2 inches from a central location; and having predetermined infrared reflectance ranges because it would be advantageous to have predetermined ranges stored in Howard's infrared reading device since it would allow a user to instantly determine whether each sample contains the analyte of interest. In addition, it would have been obvious to a person of ordinary skill in the art to incorporate Corey's method of aborting the test if the test strip is not properly inserted into the infrared reading device because it would prevent the user from repeatedly inserting the test strip incorrectly and would prevent patients from being misdiagnosed from inaccurate test results.

11. **Claims 26-27** are rejected under 35 U.S.C. 103(a) as being unpatentable over Howard in view Corey, as applied to claims 18-22 above, and further in view of Poto et al. ("Poto," US 5728352).

The teachings of Howard in view of Corey are stated above. Howard in view of Corey does not specifically teach a method incorporating obtaining information concerning the test strip is calibration information based on a particular batch, and information relating to the location of reactive areas, times, age, and reactivity. Poto teaches providing a diagnostic instrument calibrated for use with a test strip, an instrument housing having key guides defining a location at which the strip is placed and defining a test reading aperture on the strip, calibrating the electronic diagnostic instrument to a specific test strip lot, and an instrument with the ability to reject strips

that have lost so much activity (i.e. age or unusual exposure). (i.e. column 1, line 63 to column 2, line 21; column 9, lines 65-68).

It would have been obvious to a person of ordinary skill in the art to modify the modified Howard by incorporating the calibration information of Poto because it would allow a user, who discovers any unusual errors while testing, to quickly and easily obtain the particular lot of reagents or other components that were used with the sample to determine whether particular lot of reagents or other components are the factors causing the unusual results.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lore Ramillano whose telephone number is (571) 272-7420. The examiner can normally be reached on Mon. to Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO

Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lore Ramillano
Examiner
Art Unit 1743

Jill Warden
Supervisory Patent Examiner
Technology Center 1700